

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Rosen et al.

Docket No.: PF596P1N

Application No.: 10/602,727

Confirmation No.: 1552

Filed: June 25, 2003

Art Unit: 1645

For: Antibodies Against Protective Antigen

Examiner: P. A. Duffy

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of a claim of the subject application, Agent for Applicants hereby directs the Examiner's attention to references A1-A185 listed on the attached Form SB/08. Copies of non-U.S. patent references A48-A185 are attached.

Identification of the listed references is not to be construed as an admission of any individual associated with the filing or prosecution of the subject application that such references are available as "prior art" against the subject application. Furthermore, Applicants do not waive any rights to take appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the subject application.

The listed references are presented so that the Patent and Trademark Office can determine any materiality thereof to the claimed invention. See 37 C.F.R. § 1.104(a) concerning the Examiner's duty to consider and use any such information. Applicants respectfully request that the Examiner make the listed references of record in the file history of the application, and consider the information contained therein during the prosecution of this application.

Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. Accordingly, no fee is believed due.

However, should the Patent Office determine otherwise, please charge such fee to our Deposit Account No. 08-3425.

Dated: July 11, 2006

Respectfully submitted,

By Michele Shannon  
Michele Shannon

Registration No.: 47,075  
HUMAN GENOME SCIENCES, INC.  
Intellectual Property Dept.  
14200 Shady Grove Road  
Rockville, Maryland 20850  
(301) 354-3930

KKH/MJH/MS/ba

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
				Attorney Docket Number	PF596P1N
Sheet	1	of	10		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	5,591,631	01-07-1997	Leppla et al.	
	A2	5,604,201	02-18-1997	Thomas et al.	
	A3	5,677,274	10-14-1997	Leppla et al.	
	A4	5,840,312	11-24-1998	Mock et al.	
	A5	6,180,356	01-30-2001	London, E. and J.C. Sharpe	
	A6	6,224,870	05-01-2001	Segal, Andrew H.	
	A7	6,267,966	07-31-2001	Baillie, Leslie W.J.	
	A8	6,316,006	11-13-2001	Worsham et al.	
	A9	6,329,156	12-11-2001	Cirino et al.	
	A10	6,348,450	02-19-2002	Tang et al.	
	A11	6,387,665	05-14-2002	Ivins et al.	
	A12	6,770,479	08-03-2004	Lee et al.	
	A13	6,913,756	07-05-2005	Kearney, John F.	
	A14	6,916,474	07-12-2005	Harvey et al.	
	A15	6,979,449	12-27-2005	Mock, Michèle	
	A16	2001/0031264	10-18-2001	Segal, Andrew	
	A17	2002/0034512	03-21-2002	Ivins et al.	
	A18	2002/0039588	04-04-2002	Collier, J.R. and B.R. Sellman	
	A19	2002/0048590	04-25-2002	Klimpel et al.	
	A20	2002/0051791	05-02-2002	Galloway, D.R. and A.J. Mateczun	
	A21	2002/0082386	06-27-2002	Mangold et al.	
	A22	2002/0120106	08-29-2002	Bogoch, S. and E.S. Bogoch	
	A23	2002/0142002	10-03-2002	Galloway, D.R. and A.J. Mateczun	
	A24	2002/0197272	12-26-2002	Galloway, D.R. and A.J. Mateczun	
	A25	2003/0003109	01-02-2003	Galloway, D.R. and A.J. Mateczun	
	A26	2003/0059937	03-27-2003	Ruben et al.	
	A27	2003/0118591	06-26-2003	Levy, Joshua	
	A28	2003/0198595	10-23-2003	Goldenberg et al.	
	A29	2003/0235594	12-25-2003	Humphreys, R. and M. Xu	
	A30	2004/0009178	01-15-2004	Bowdish et al.	
	A31	2004/0009182	01-15-2004	Myers, R.C. and A.T. Waytes	
	A32	2004/0014707	01-22-2004	Cirino et al.	
	A33	2004/0028695	02-12-2004	Park, S. and Giri, L.	
	A34	2004/0058881	03-25-2004	Humphreys, R. and M. Xu	
	A35	2004/0166120	08-26-2004	Thomas et al.	
	A36	2004/0170967	09-02-2004	Lee et al.	
	A37	2004/0171121	09-02-2004	Leppla et al.	
	A38	2004/0235136	11-25-2004	Singh, Y. and H. Khanna	
	A39	2004/0258699	12-23-2004	Bowdish et al.	
	A40	2005/0106647	05-19-2005	Harvey et al.	
	A41	2005/0123900	06-09-2005	Dimitrov et al.	
	A42	2005/0136049	06-23-2005	Ledbetter et al.	
	A43	2005/0267294	12-01-2005	Harvey et al.	
	A44	2005/0281830	12-22-2005	Morrow et al.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	2	of	10	Attorney Docket Number	PF596P1N

	A45	2005/0287149	12-29-2005	Keler et al.	
	A46	2006/0002947	01-05-2006	Humphreys, R. and M. Xu	
	A47	2006/0121045	06-08-2006	Iverson et al.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	3	of	10	Attorney Docket Number	PF596P1N

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>2</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A48	WO94/18332-A2	08-18-1994	The Government of the United States of America, as represented by The Secretary of the Department of Health and Human Services		
	A49	EP 0 934 953-A2	08-11-1999	Boehringer Mannheim Corporation		
	A50	WO99/57266-A2	11-11-1999	Imperial College Innovations Limited		
	A51	WO00/02522-A3	01-20-2000	U.S. Medical Research Institute of Infectious Diseases		
	A52	WO01/45639-A2	06-28-2001	The Ohio State University Research Foundation		
	A53	WO01/58956-A2	08-16-2001	BASF Aktiengesellschaft		
	A54	WO01/82788-A3	11-08-2001	President and Fellows of Harvard College		
	A55	WO02/04646-A1	01-17-2002	The Secretary of State for Defence		
	A56	WO02/096467-A2	12-05-2002	Microbiological Research Authority		
	A57	WO03/010316-A1	02-06-2003	Regma Bio Technologies Ltd		
	A58	WO03/087129-A2	10-23-2003	Plexus Vaccine, Inc.		
	A59	WO03/087378-A1	10-23-2003	Powderject Research Limited		
	A60	WO04/002415-A2	01-08-2004	Dana-Farber Cancer Institute, Inc.		
	A61	WO04/003139-A2	01-08-2004	Human Genome Sciences, Inc.		
	A62	EP 1 382 615-A1	01-21-2004	Xerion Pharmaceuticals AG		
	A63	WO04/024067-A2	03-25-2004	Vical Incorporated		
	A64	WO04/037861-A2	05-06-2004	Wyeth; Cambridge Antibody Technology		
	A65	WO04/056874-A2	07-08-2004	Xerion Pharmaceuticals AG and Tufts University		
	A66	WO04/072117-A2	08-26-2004	Pharmacia Corporation		
	A67	GB 2 400 851-A	10-27-2004	BiolInvent International AB		
	A68	WO04/113522-A1	12-29-2004	Direvo Biotech AG		
	A69	WO05/000884-A1	01-06-2005	The Government of the United States of America, as represented by The Secretary of the Department of Health and Human Services		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	4	of	10	Attorney Docket Number	PF596P1N

	A70	WO05/004791-A2	01-20-2005	President and Fellows of Harvard College; The Board of Regents of the University of Oklahoma		
	A71	WO05/007804-A2	01-27-2005	President and Fellows of Harvard College; The Brigham and Women's Hospital, Inc.		
	A72	WO05/034841-A2	04-21-2005	Merck & Co., Inc.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
				Attorney Docket Number	PF596P1N
Sheet	5	of	10		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A73	"Anthrax," Internet publication by National Organization of Rare Disorders (NORD), 2001.	
	A74	"Anthrax: Current, comprehensive information on pathogenesis, microbiology, epidemiology, diagnosis, treatment, and prophylaxis," published by Center for Infectious Disease Research & Policy (CIDRAP) Academic Health Center -- University of Minnesota (Jul. 23, 2003).	
	A75	"Anthrax", Chapter 19 of <i>Epidemiology &amp; Prevention of Vaccine-Preventable Diseases</i> , Centers for Disease Control and Prevention, 7 <sup>th</sup> ed., Washington, DC: Public Health Foundation, 2002.	
	A76	"Summary of Notifiable Diseases -- United States, 2001," in <i>Morbidity &amp; Mortality Weekly Report</i> , published by Centers for Disease Control & Prevention, 50(53):1-108 (May 2, 2003) (selected pages).	
	A77	"Suspected Cutaneous Anthrax in a Laboratory Worker -- Texas, 2002," in <i>Morbidity &amp; Mortality Weekly Report</i> , published by Centers for Disease Control & Prevention, 51(13):279-281 (Apr. 5, 2002).	
	A78	"The Anthrax Vaccine: Is It Safe? Does It Work?," JOELLENBECK et al., eds., Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, Medical Follow-Up Agency, Institute of Medicine, National Academy Press, Washington, D.C. (March 2002) (4 pp).	
	A79	"Update: Investigation of Bioterrorism-Related Anthrax and Interim Guidelines for Clinical Evaluation of Persons with Possible Anthrax," in <i>Morbidity &amp; Mortality Weekly Report</i> , published by Centers for Disease Control & Prevention, 50(43):941-948 (Nov. 2, 2001).	
	A80	ABRAMOVA et al., "Pathology of inhalational anthrax in 42 cases from the Sverdlovsk outbreak of 1979," <i>Proc. Natl. Acad. Sci. USA</i> , 90:2291-2294 (Mar. 1993).	
	A81	Anthrax Fact Sheet. Internet publication by Office of Communications & Public Liaison, National Institute of Allergy and Infectious Diseases (May 2002).	
	A82	ATHAMNA et al., "In vitro susceptibility of <i>Bacillus anthracis</i> to various antibacterial agents and their time-kill activity," <i>J. Antimicrobiol. Chemother.</i> , 53:247-251 (2004).	
	A83	BARAKAT et al., "Fatal Inhalational Anthrax in a 94-Year-Old Connecticut Woman," <i>JAMA</i> , 287:863-868 (Feb. 20, 2002) (reprinted).	
	A84	BARNARD, et al., "Vaccination against Anthrax with Attenuated Recombinant Strains of <i>Bacillus anthracis</i> That Produce Protective Antigen," <i>Infect. Immun.</i> , 67:562-567 (Feb. 1999).	
	A85	BEAUREGARD et al., "Proteolytic activation of receptor-bound anthrax protective antigen on macrophages promotes its internalization," <i>Cell. Microbiol.</i> , 2:251-258 (2000).	
	A86	BioPort, Inc., Anthrax Vaccine Adsorbed (Biothrax™) Product Insert (Jan. 31, 2002).	
	A87	BOHANNON, JOHN, "From Bioweapons Backwater to Main Attraction," <i>Science</i> , 300:414-415 (Apr. 18, 2003).	
	A88	BRADLEY et al., "Identification of the cellular receptor for anthrax toxin," <i>Nature</i> , 414:225-229 (Nov. 8, 2001).	
	A89	BREGENHOLT, S. and J. HAURUM, "Pathogen-specific recombinant human polyclonal antibodies: biodefence applications," <i>Expert Opin. Biol. Ther.</i> , 4:387-396 (2004).	
	A90	BROOK et al., "In vitro resistance of <i>Bacillus anthracis</i> Sterne to doxycycline, macrolides and quinolones," <i>Int. J. Antimicrob. Agents</i> , 18:559-562 (2001).	
	A91	BROSSIER et al., "Role of Toxin Functional Domains in Anthrax Pathogenesis," <i>Infect. Immun.</i> , 68:1781-1786 (Apr. 2000).	
	A92	BROSSIER et al., "Anthrax Spores Make an Essential Contribution to Vaccine Efficacy," <i>Infect. Immun.</i> , 70:661-664 (Feb. 2002).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	6	of	10	Attorney Docket Number	PF596P1N

A93	CASADEVALL, A., "Antibodies for defense against biological attack," <i>Nature Biotech.</i> , 20:114 (Feb. 2002).	
A94	CASADEVALL, A., "Passive Antibody Administration (Immediate Immunity) as a Specific Defense against Biological Weapons," <i>Emerg. Infect. Dis.</i> , 8:833-841 (Aug. 2002).	
A95	CASBOHM et al., "Flow cytometric analysis of protective antigen-stimulated T cell cytokine production and proliferation in rhesus macaques challenged with aerosolized bacillus anthracis spores," presented at Proceedings of the 45th Annual Meeting and ToxExpo, Society of Toxicology (SOT), San Diego, CA, March 5-9, 2006 (poster).	
A96	CHANG et al., Endemic, Notifiable Bioterrorism-Related Diseases, United States, 1992-1999," <i>Emerg. Infect. Dis.</i> , 9:556-564 (May 2003).	
A97	CHAUDRY et al., "Quickening the pace of anthrax research: three advances point towards possible therapies," <i>Trends Microbiol.</i> , 10:58-62 (Feb. 2002).	
A98	CIESLAK, T.J. and E.M. EITZEN, "Clinical and Epidemiologic Principles of Anthrax," <i>Emerg. Infect. Dis.</i> , 5:552-555 (Jul.-Aug. 1999).	
A99	CIRINO et al., "Disruption of Anthrax Toxin Binding with the Use of Human Antibodies and Competitive Inhibitors," <i>Infect. Immun.</i> , 67:2957-2963 (Jun. 1999).	
A100	COKER et al., " <i>Bacillus anthracis</i> Virulence in Guinea Pigs Vaccinated with Anthrax Vaccine Adsorbed is Linked to Plasmid Quantities and Clonality," <i>J. Clin. Microbiol.</i> , 41:1212-1218 (Mar. 2003).	
A101	CUI et al., "Lethality during continuous anthrax lethal toxin infusion is associated with circulatory shock but not inflammatory cytokine or nitric oxide release in rats," <i>Am. J. Physiol. Regul. Integr. Comp. Physiol.</i> , 286:R699-R709 (2004).	
A102	CUI et al., "Late Treatment with a Protective Antigen-Directed Monoclonal Antibody Improves Hemodynamic Function and Survival in a Lethal Toxin-Infused Rat Model of Anthrax Sepsis," <i>J. Infect. Dis.</i> , 191:422-434 (2005).	
A103	CUNNINGHAM et al., "Mapping the lethal factor and edema factor binding sites on oligomeric anthrax protective antigen," <i>PNAS</i> , 99:7049-7053 (May 14, 2002).	
A104	DIXON et al., "Anthrax," <i>N. Engl. J. Med.</i> , 341:815-826 (Sep. 9, 1999).	
A105	ESCUYER, V. and R.J. COLLIER, "Anthrax Protective Antigen Interacts with a Specific Receptor on the Surface of CHO-K1 Cells," <i>Infect. Immun.</i> , 59:3381-3386 (Oct. 1991).	
A106	EZZELL et al., "Immunoelectrophoretic Analysis, Toxicity, and Kinetics of In Vitro Production of the Protective Antigen and Lethal Factor Components of <i>Bacillus anthracis</i> Toxin," <i>Infect. Immun.</i> , 45:761-767 (Sep. 1984).	
A107	EZZELL, J.W. and T.G. ABSHIRE, "Serum protease cleavage of <i>Bacillus anthracis</i> protective antigen," <i>J. Gen. Microbiol.</i> , 138:543-549 (1992).	
A108	FARCHAUS et al., "Fermentation, Purification, and Characterization of Protective Antigen from a Recombinant, Avirulent Strain of <i>Bacillus anthracis</i> ," <i>Appl. Environ. Microbiol.</i> , 64:982-991 (Mar. 1998).	
A109	FELLOWS et al., "Efficacy of a human anthrax vaccine in guinea pigs, rabbits, and rhesus macaques against challenge by <i>Bacillus anthracis</i> isolates of diverse geographical origin," <i>Vaccine</i> , 19:3241-3247 (2001).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--



Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	7	of	10	Attorney Docket Number	PF596P1N

A110	FRIEDLANDER, A.M., "Chapter 22: Anthrax," in <i>Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare. Specialty eds:</i> Sidell, F.R., et al., (The Office of the Surgeon General at TMM Publications, Borden Institute, Walter Reed Army Medical Center, Washington, DC) pp. 467-478 (1997).
A111	FRIEDLANDER, A.M., "Anthrax: Clinical Features, Pathogenesis, and Potential Biological Warfare Threat," <i>Curr. Clin. Topics Infect. Dis.</i> , 20:335-349 (2000).
A112	FRIEDLANDER, A.M., "Tackling anthrax," <i>Nature</i> , 414:160-161 (Nov. 8, 2001).
A113	FRIEDLANDER et al., "Postexposure Prophylaxis against Experimental Inhalation Anthrax," <i>J. Infect. Dis.</i> , 167:1239-1243 (May 1993).
A114	FRIEDLANDER et al., "Anthrax Vaccine Evidence for Safety and Efficacy Against Inhalational Anthrax," <i>JAMA</i> , 282:2104-2106 (Dec. 8, 1999).
A115	GEIER, M.R. and D.A. GEIER, "Gastrointestinal Adverse Reactions Following Anthrax Vaccination: An Analysis of the Vaccine Adverse Events Reporting System (VAERS) Database," <i>Hepato-Gastroenterol.</i> , 51:762-767 (2004).
A116	GORDON et al., "Inhibitors of Receptor-Mediated Endocytosis Block the Entry of <i>Bacillus anthracis</i> Adenylate Cyclase Toxin but Not That of <i>Bordetella pertussis</i> Adenylate Cyclase Toxin," <i>Infect. Immun.</i> , 56:1066-1069 (May 1988).
A117	HANNA et al., "On the role of macrophages in anthrax," <i>Proc. Natl. Acad. Sci. USA</i> , 90:10198-10201 (Nov. 1993).
A118	HERING et al., "Validation of the anthrax lethal toxin neutralization assay," <i>Biologicals</i> , 32:17-27 (2004).
A119	HOLTY et al., "Systematic Review: A Century of Inhalational Anthrax Cases from 1900 to 2005," <i>Ann. Intern. Med.</i> 144:270-280 (2006).
A120	INGLESBY et al., "Anthrax as a Biological Weapon, 2002 Updated Recommendations for Management," <i>JAMA</i> , 287:2236-2252 (May 1, 2002); (reprinted with corrections as set forth in <i>JAMA</i> 288:1849 (Oct. 16, 2002)).
A121	IVINS et al., "Comparative efficacy of experimental anthrax vaccine candidates against inhalation anthrax in rhesus macaques," <i>Vaccine</i> , 16:1141-1148 (1998).
A122	IVINS et al., "Influence of Body Weight on Response of Fischer 344 Rats to Anthrax Lethal Toxin," <i>Appl. Environ. Microbiol.</i> , 55:2098-2100 (Aug. 1989).
A123	IVINS et al., "Efficacy of a standard human anthrax vaccine against <i>Bacillus anthracis</i> aerosol spore challenge in rhesus monkeys," <i>Salisbury Medical Bulletin</i> , Special Supplement No. 87, pages 125-126 (1996).
A124	JEFFERDS, et al., "Adherence to Antimicrobial Inhalational Anthrax Prophylaxis among Postal Workers, Washington, D.C., 2001," <i>Emerg. Infect. Dis.</i> , 8:1138-1144 (Oct. 2002).
A125	JERNIGAN et al., "Bioterrorism-Related Inhalational Anthrax: The First 10 Cases Reported in the United States," <i>Emerg. Infect. Dis.</i> , 7:933-944 (Nov.-Dec. 2001).
A126	JERNIGAN et al., "Investigation of Bioterrorism-Related Anthrax, United States, 2001: Epidemiologic Findings," <i>Emerg. Infect. Dis.</i> , 8:1019-1028 (Oct. 2002).
A127	KLIMPEL et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci. USA</i> , 89:10277-10281 (Nov. 1992).
A128	KOBILER et al., "Efficiency of Protection of Guinea Pigs against Infection with <i>Bacillus anthracis</i> Spores by Passive Immunization," <i>Infect. Immun.</i> , 70:544-550 (Feb. 2002).
A129	LANGERMANN et al., "Therapeutic Potential of Dominant Negative Inhibitor (DNI) Following Spore Challenge in New Zealand White (NZW) Rabbits," presented at 44 <sup>th</sup> Interscience Conference on Antimicrobial Agents & Chemotherapy (ICAAC), Washington, DC, October 30-November 2, 2004 (abstract only).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	8	of	10	Attorney Docket Number	PF596P1N

A130	LEPPLA, S.H., "Anthrax toxin edema factor: A bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," <i>Proc. Natl. Acad. Sci. USA</i> , 79:3162-3166 (May 1982).	
A131	LEPPLA, S.H., "A dominant-negative therapy for anthrax," <i>Nature Med.</i> , 7:659-660 (Jun. 2001).	
A132	LEPPLA et al., "Development of an improved vaccine for anthrax," <i>J. Clin. Invest.</i> , 110:141-144 (Jul. 2002).	
A133	LITTLE, S.F. and B.F. IVINS, "Molecular Pathogenesis of <i>Bacillus anthracis</i> Infection," <i>Microbes Infect.</i> , 2:131-139 (1999).	
A134	LITTLE et al., "Production and Characterization of Monoclonal Antibodies against the Lethal Factor Component of <i>Bacillus anthracis</i> Lethal Toxin," <i>Infect. Immun.</i> , 58:1606-1613 (Jun. 1990).	
A135	LITTLE et al., "Characterization of lethal factor binding and cell receptor binding domains of protective antigen of <i>Bacillus anthracis</i> using monoclonal antibodies," <i>Microbiology</i> , 142:707-715 (1996).	
A136	LITTLE et al., "Passive Protection by Polyclonal Antibodies against <i>Bacillus anthracis</i> Infection in Guinea Pigs," <i>Infect. Immun.</i> , 65:5171-5175 (Dec. 1997).	
A137	LITTLE et al., "Defining a serological correlate of protection in rabbits for a recombinant anthrax vaccine," <i>Vaccine</i> , 22:422-430 (2004).	
A138	MAHAN et al., "Anthrax Vaccination and Self-reported Symptoms, Functional Status, and Medical Conditions in the National Health Survey of Gulf War Era Veterans and Their Families," <i>Ann. Epidemiol.</i> , 14:81-88 (2004).	
A139	MARCUS et al., "Contribution of Immunological Memory to Protective Immunity Conferred by a <i>Bacillus anthracis</i> Protective Antigen-Based Vaccine," <i>Infect. Immun.</i> , 72:3471-3477 (Jun. 2004).	
A140	MAYNARD et al., "Protection against anthrax toxin by recombinant antibody fragments correlates with antigen affinity," <i>Nature Biotech.</i> , 20:597-601 (Jun. 2002).	
A141	MESELSON et al., "The Sverdlovsk Anthrax Outbreak of 1979," <i>Science</i> , 266:1202-1208 (Nov. 18, 1994).	
A142	MILNE, J.C. and R.J. COLLIER, "pH-dependent permeabilization of the plasma membrane of mammalian cells by anthrax protective antigen," <i>Mol. Microbiol.</i> , 10:647-653 (1993).	
A143	MOGRIDGE et al., "The lethal and edema factors of anthrax toxin bind only to oligomeric forms of the protective antigen," <i>PNAS</i> , 99:7045-7048 (May 14, 2002).	
A144	MOHAMED et al., "A High-Affinity Monoclonal Antibody to Anthrax Protective Antigen Passively Protects Rabbits before and after Aerosolized <i>Bacillus anthracis</i> Spore Challenge," <i>Infect. Immun.</i> , 73:795-802 (Feb. 2005).	
A145	MOUREZ et al., "Designing a polyvalent inhibitor of anthrax toxin," <i>Nature Biotech.</i> , 19:958-961 (Oct. 2001).	
A146	OKINAKA et al., "Sequence and Organization of pXO1, the Large <i>Bacillus anthracis</i> Plasmid Harboring the Anthrax Toxin Genes," <i>J. Bacteriol.</i> , 181:6509-6515 (Oct. 1999).	
A147	PEZARD et al., "Contribution of Individual Toxin Components to Virulence of <i>Bacillus anthracis</i> ," <i>Infect. Immun.</i> , 59:3472-3477 (Oct. 1991).	
A148	PEZARD et al., "Protective Immunity Induced by <i>Bacillus anthracis</i> Toxin-Deficient Strains," <i>Infect. Immun.</i> , 63:1369-1372 (Apr. 1995).	
A149	PITT et al., "In vitro correlate of immunity in a rabbit model of inhalational anthrax," <i>Vaccine</i> , 19:4768-4773 (2001).	
A150	PRICE et al., "Genetic Diversity in the Protective Antigen Gene of <i>Bacillus anthracis</i> ," <i>J. Bacteriol.</i> , 181:2358-2362 (Apr. 1999).	

Examiner Signature	Date Considered
--------------------	-----------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	9	of	10	Attorney Docket Number	PF596P1N

A151	QUINN et al., "Functional Mapping of Anthrax Toxin Lethal Factor by In-frame Insertion Mutagenesis," <i>J. Biol. Chem.</i> , 266:20124-20130 (Oct. 25, 1991).	
A152	QUINN et al., "Specific, Sensitive, and Quantitative Enzyme-Linked Immunosorbent Assay for Human Immunoglobulin G Antibodies to Anthrax Toxin Protective Antigen," <i>Emerg. Infect. Dis.</i> , 8:1103-1110 (Oct. 2002).	
A153	RAMIREZ et al., "Production, recovery and immunogenicity of the protective antigen from a recombinant strain of <i>Bacillus anthracis</i> ," <i>J. Indust. Microbiol. Biotech.</i> , 28:232-238 (2002).	
A154	READ et al., "Comparative Genome Sequencing for Discovery of Novel Polymorphisms in <i>Bacillus anthracis</i> ," <i>Science</i> , 296:2028-2033 (Jun. 14, 2002).	
A155	REED et al., "Mapping of Antibody Responses to the Protective Antigen of <i>Bacillus anthracis</i> by Flow Cytometric Analysis," <i>Cytometry</i> , 49:1-7 (2002).	
A156	REUVENY et al., "Search for Correlates of Protective Immunity Conferred by Anthrax Vaccine," <i>Infect. Immun.</i> , 69:2888-2893 (May 2001).	
A157	RUSSELL, P.K., "Vaccines in Civilian Defense Against Bioterrorism," <i>Emerg. Infect. Dis.</i> , 5:531-533 (Jul.-Aug. 1999).	
A158	SABOURIN et al., "Short Duration Ciprofloxacin® Therapy Provides High Protection to Non-Human Primates Challenged With Aerosolized <i>B. Anthracis</i> Spores," presented at Bacillus ACT Conference-2005, Santa Fe, NM, September 25-29, 2006 (abstract only).	
A159	SAILE et al., "Control of Anthrax Toxin Gene Expression by the Transition State Regulator <i>abrB</i> ," <i>J. Bacteriol.</i> , 184:370-380 (Jan. 2002).	
A160	SASTRY et al., "Identification of <i>Bacillus anthracis</i> by a simple protective antigen-specific mAb dot-ELISA," <i>J. Med. Microbiol.</i> , 52:47-49 (2003).	
A161	SAWADA-HIRAI et al., "Human anti-anthrax protective antigen neutralizing monoclonal antibodies derived from donors vaccinated with anthrax vaccine adsorbed," <i>J. Immune Based Therapies and Vaccines</i> , 2:5 (2004).	
A162	SCOBIE et al., "Human capillary morphogenesis protein 2 functions as an anthrax toxin receptor," <i>PNAS</i> , 100:5170-5174 (Apr. 29, 2003).	
A163	SELLMAN et al., "Point Mutations in Anthrax Protective Antigen That Block Translocation," <i>J. Biol. Chem.</i> 276:8371-8376 (Mar. 16, 2001).	
A164	SELLMAN et al., "Dominant-Negative Mutants of a Toxin Subunit: An Approach to Therapy of Anthrax," <i>Science</i> , 292:695-697 (Apr. 27, 2001).	
A165	SHEPARD et al., "Antimicrobial Postexposure Prophylaxis for Anthrax: Adverse Events and Adherence," <i>Emerg. Infect. Dis.</i> , 8:1124-1132 (Oct. 2002).	
A166	SINGH et al., "The Carboxyl-terminal End of Protective Antigen Is Required for Receptor Binding and Anthrax Toxin Activity," <i>J. Biol. Chem.</i> , 266:15493-15497 (Aug. 15, 1991).	
A167	SINGH et al., "Study of Immunization against Anthrax with the Purified Recombinant Protective Antigen of <i>Bacillus anthracis</i> ," <i>Infect. Immun.</i> , 66:3447-3448 (Jul. 1998).	
A168	SINGH et al., "A Dominant Negative Mutant of <i>Bacillus anthracis</i> Protective Antigen Inhibits Anthrax Toxin Action <i>in Vivo</i> ," <i>J. Biol. Chem.</i> , 276:22090-22094 (Jun. 22, 2001).	
A169	SUBRAMANIAN et al., "A Phase 1 Study of PAmAb, a Fully Human Monoclonal Antibody against <i>Bacillus anthracis</i> Protective Antigen, in Healthy Volunteers," <i>Clin. Infect. Dis.</i> , 41:12-20 (Jul. 1, 2005).	
A170	SWARTZ, M.N., "Recognition and Management of Anthrax - An Update," <i>N. Engl. J. Med.</i> , 345:1621-1626 (Nov. 29, 2001).	
A171	VASCONCELOS et al., "Pathology of Inhalation Anthrax in Cynomolgus Monkeys ( <i>Macaca fascicularis</i> )," <i>Lab. Invest.</i> , 83:1201-1209 (Aug. 2003).	
A172	VAUGHAN et al., "Human Antibodies with Sub-nanomolar Affinities Isolated from a Large Non-immunized Phage Display Library," <i>Nature Biotech.</i> , 14:309-314 (Mar. 1996).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/602,727-Conf. #1552
				Filing Date	June 25, 2003
				First Named Inventor	Craig A. Rosen
				Art Unit	1645
				Examiner Name	P.A. Duffy
Sheet	10	of	10	Attorney Docket Number	PF596P1N

A173	VIETRI et al., "Short-course postexposure antibiotic prophylaxis combined with vaccination protects against experimental inhalational anthrax infection," presented at Proceedings of the 43 <sup>rd</sup> Annual Meeting of Infectious Diseases Society of America (IDSA) San Francisco, CA, October 6-9, 2006 (poster).	
A174	VODKIN, M.H. and S.H. LEPPLA., "Cloning of the Protective Antigen Gene of <i>Bacillus anthracis</i> ," <i>Cell</i> , 34:693-697 (Sep. 1983).	
A175	WEIN et al., "Emergency response to an anthrax attack," <i>PNAS</i> , 100:4346-4351 (Apr. 1, 2003).	
A176	WELKOS et al., "Sequence and analysis of the DNA encoding protective antigen of <i>Bacillus anthracis</i> ," <i>Gene</i> , 69:287-300 (1988).	
A177	WELKOS et al., "Non-toxigenic derivatives of the Ames strain of <i>Bacillus anthracis</i> are fully virulent for mice: role of plasmid pX02 and chromosome in strain-dependent virulence," <i>Microb. Pathog.</i> , 14:381-388 (1993).	
A178	WELKOS et al., "The role of antibodies to <i>Bacillus anthracis</i> and anthrax toxin components in inhibiting the early stages of infection by anthrax spores," <i>Microbiology</i> , 147:1677-1685 (2001).	
A179	WELKOS et al., "In-vitro characterisation of the phagocytosis and fate of anthrax spores in macrophages and the effects of anti-PA antibody," <i>J. Med. Microbiol.</i> , 51:821-831 (2002).	
A180	WILD et al., "Human antibodies from immunized donors are protective against anthrax toxin <i>in vivo</i> ," <i>Nature Biotech.</i> , 21:1305-1306 (Nov. 2003).	
A181	WILLIAMS et al., "Anthrax Postexposure Prophylaxis in Postal Workers, Connecticut, 2001," <i>Emerg. Infect. Dis.</i> , 8:1133-1137 (Oct. 2002).	
A182	YOUNG, J.A.T. and R.J. COLLIER, "Attacking anthrax," <i>Sci. Am.</i> , 286:48-50, 54-59 (2002).	
A183	ZAUCHA et al., "The Pathology of Experimental Anthrax in Rabbits Exposed by Inhalation and Subcutaneous Inoculation," <i>Arch. Pathol. Lab. Med.</i> , 122:982-992 (1998).	
A184	ZHOU et al., "Human antibodies against spores of the genus <i>Bacillus</i> : A model study for detection of and protection against anthrax and the bioterrorist threat," <i>PNAS</i> , 99:5241-5246 (Apr. 16, 2002).	
A185	ZILINSKAS, R. A., "Iraq's Biological Weapons-The Past as Future?," <i>JAMA</i> , 278:418-424 (Aug. 6, 1997).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--